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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of Allogeneic T Cell and Gene Therapy Vector Chimeric Antigen Receptor (CAR) Therapies Targeting CD22 Alone or in Combination with CARs Targeting CD19 for the Treatment of B-Cell Malignancies

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this Notice to Sana Biotechnology Inc. Life Sciences Inc., ("Sana"), located in Seattle, Washington**.**

DATES: Only written comments and/or complete applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Jim Knabb, Senior Technology Transfer Manager, at Telephone: (240)-276-7856; or at E-mail: jim.knabb@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

E-080-2012-0: Human Monoclonal Antibodies Specific for CD22

1. US Provisional Patent Application 61/042,329, filed April 4, 2008 (E-080-2008-0-US-01);
2. International Patent Application PCT/US2009/039,080, Filed April 1, 2009 (E-080-2008/0-PCT-02);

3. US Patent Application: 12/934,214, filed September 23, 2010 (E-080-2008-0-US-03);
4. US Patent Application 13/959,061, filed August 5, 2015 (E-080-2008-0-US-04);
5. US Patent Application 15/012,023, filed February 1, 2016 (E-080-2008-0-US-05);
6. US Patent Application 15/424,238, filed February 3, 2017 (E-080-2008-0-US-06).

E-291-2012-0: M971 Chimeric Antigen Receptors

1. US Provisional Patent Application 61/717,960, filed October 24, 2012 (E-291-2012-0-US-01);
2. International Patent Application PCT/US2013/060332, filed September 18, 2013 (E-291-2012-0-PCT-02);
3. Australia Patent Application No: 2019235926, filed September 2, 2020 (E-291-2012-0-AU-03);
4. Brazil Patent Application BR112015009003-6, filed April 22, 2015 (E-291-2012-0-BR-04);
5. Canada Application No: 2889055, filed September 18, 2013 (E-291-2012-0-CA-05);
6. China Application No: 201380061387.5, filed May 25, 2015 (E-291-2012-0-CN-06);
7. European Patent Application No: 13773468.7, filed September 18, 2013 (E-291-2012-0-EP-07);
8. India Patent Application No: 2344/CHENP/2015, filed September 18, 2013 (E-291-2012-0-IN-08);
9. Japan Application No: 539602/2015, filed April 24, 2015 (E-291-2012-0-JP-09);
10. Russia Patent Application: 2015117237, filed May 7, 2015 (E-291-2012-0-RU-10);
11. US Patent Application: 14/437,889, filed April 23, 2015 (E-291-2012-0-US-11);
12. Hong Kong Patent Application: 16101891.0, filed February 19, 2016 (E-291-2012-0-HK-12);
13. Russia Patent Application: 2018116582, filed May 4, 2018 (E-291-2012-0-RU-13);
14. Japan Patent Application: 2018-088908, filed May 2, 2018, (E-291-2012-0-JP-14);
15. Australia Patent Application: 2018204257, filed June 14, 2018 (E-291-2012-0-AU-16);

16. US Patent Application: 16/107,271, filed August 21, 2018 (E-291-2012-0-US-17);
17. Germany Patent Application: 13773468.7, filed April 22, 2015 (E-291-2012-0-DE-18);
18. Spain Patent Application: 13773468.7, filed April 22, 2015 (E-291-2012-0-ES-19);
19. France Patent Application: 13773468.7, filed April 22, 2015 (E-291-2012-0-FR-20);
20. Great Britain Patent Application: 13773468.7, filed April 22, 2015 (E-291-2012-0-GB-21);
21. Italy Patent Application: 13773468.7, filed April 22, 2015 (E-291-2012-0-IT-22);
22. China Patent Application: 201910500128.7, filed June 11, 2019 (E-291-2012-0-CN-23);
23. US Patent Application: 16/869,792, filed May 8, 2020 (E-291-2012-0-US-24).

E-106-2015-0: Chimeric Antigen Receptors Targeting Both CD19 and CD22

1. US Provisional Patent Application No.: 62/135,442, filed March 19, 2015 (E-106-2015-0-US-01)
2. International Patent Application PCTUS2016/023055, Filed March 18, 2016 (E-106-2015-0-PCT-02)
3. US Patent Application: 15/559,485. Filed September 19, 2017 (E-106-2015-0-US-03)

E-017-2017-0: CD19/CD22 Bicistronic CAR Targeting Human B-Cell Malignancies

1. US Provisional Patent Application No.: 62/135,442, filed May 15, 2017 (E-017-2017-0-US-01)
2. International Patent Application PCT/US2018/032,809, filed May 15, 2018 (E-017-2017-0-PCT-02)
3. Australia Patent Application No.: 2018269194, filed October 28, 2019 (E-017-2017-0-AU-03
4. Canada Patent Application No: 3062433, filed May 15, 2018 (E-017-2017-0-CA-04)
5. China Patent Application No.: 201880032676.5, filed Date: May 15, 2018 (E-017-2017-0-CN-05)
6. European Patent Application No.: 18733012.1, filed May 15, 2018 (E-017-2017-0-EP-06)
7. Japan Patent Application No.: 2019-563082, filed November 13, 2019 (E-017-2017-0-JP-07)
8. Korea Patent Application No.: 2019-7017289, filed December 13, 2019, (E-017-2017-0-KR-08)
9. Singapore Patent Application No.: 11201910499V, filed November 11, 2019 (E-017-2017-0-SG-09)

10. United States Patent Application No.: 16/613,187, filed November 13, 2019 (E-017-2017-0-US-10)

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide, and the fields of use may be limited to the following:

"Field 1: "Ex vivo allogeneic CAR-T"

The development, manufacture and commercialization of chimeric antigen receptor T cells (CAR-T cells) for the treatment of B cell malignancies, wherein the CAR-T cells are engineered to express a CAR that comprises the m971 binder and is mono-specific for CD22, or is specific to both CD22 and CD19 (but are not engineered to bind to any other B cell antigen), and the engineered CAR-T cells are generated *ex vivo* using allogeneic T cells that are engineered to over-express CD47.

Field 2: "In vivo gene therapy vector"

The development, manufacture and commercialization of gene therapy vectors encoding a chimeric antigen receptor construct (CAR construct), wherein the CAR construct comprises either (i) a CD22 binder m971 or (ii) the CD22 binder m971 and a CD19 binder, but, in each case (i) and (ii), comprises no other binder against a B cell antigen. For the avoidance of doubt, the field of use excludes development, manufacture and commercialization of genetically modified autologous T cells made by obtaining a patient's T cells via a standard leukapheresis procedure, genetically modifying the T cells *ex vivo*, expanding the T cells in cell culture, and formulating the T cells for later administration to the patient."

This technology discloses CAR therapies that target CD22 alone or in combination with CD19 by utilizing the anti-CD22 binder known as m971. CD22 and CD19 are expressed on the surface of B cells in B cell malignancies and CAR-T utilizing binders targeting CD 19 and CD22 have shown early promise in clinical trials for B cell malignancies.

This Notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published Notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information from these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 USC 552.

Dated: September 7, 2021.

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

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